4 510(k) Summary of Safety and Effectiveness

Manufacturer/Sponsor	Arthrex, Inc.1370 Creekside Boulevard Naples, Florida 34108-1945
510(k) Contact	Mariela Cabarcas Regulatory Affairs Associate Telephone: 239/643.5553, ext. 1246 Fax: 239/598.5508 Email: mcabarcas@arthrex.com JAN 17 2008
Trade Name	**Arthrex ProStop Plus™ Arthroereisis Subtalar Implant**
Common Name	Screw, Fixation, Bone
Product Code - Classification Name	**HWC** -Screw, Fixation, Bone
Predicate Device	MBA Resorb Implant: K051611
Device Description and Intended Use	The **Arthrex ProStop™ Plus Arthroereisis Subtalar Implant** is a fully threaded, cannulated, tapered screw. It is similar in design to the predicate device MBA Resorb Implant, K051611. The **Arthrex ProStop™ Plus Arthroereisis Subtalar Implants** are indicated as an internal support to primary surgical interventions in the treatment of flat foot, providing structural support at minimum during the first three months of healing.
Substantial Equivalence Summary	The **Arthrex ProStop™ Plus Arthroereisis Subtalar Implant** is substantially equivalent to the predicate the predicate device MBA Resorb Implant, K051611, in which the basic features and intended uses are the same. Any differences between the ProStop™ Plus Arthroereisis Subtalar Implant and the predicate K051611 are considered minor and do not raise questions concerning safety and effectiveness. Based on the information submitted, Arthrex, Inc. has determined that the new ProStop™ Plus Arthroereisis Subtalar Implant is substantially equivalent to the currently marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 17 2008

Arthrex, Inc.
% Ms. Mariela Cabarcas
Regulatory Affairs Associate
1370 Creekside Boulevard
Naples, Florida 34108-1945

Re: K071456
Trade/Device Name: ProStop Plus Arthroereisis Subtalar Implant
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: MAI, HWC
Dated: January 9, 2008
Received: January 10, 2008

Dear Ms. Cabarcas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

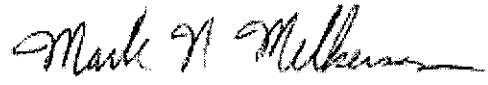
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3 Indications for Use Form

Indications for Use

510(k) Number: K071456

Device Name: **Arthrex ProStop™ Plus Arthroereisis Subtalar Implant**

The **Arthrex ProStop™ Plus Arthroereisis Subtalar Implants** are indicated as an internal support to primary surgical interventions in the treatment of flat foot, providing structural support at minimum during the first three months of healing.

Prescription Use _X_ AND/OR Over-The-Counter Use _____

(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buchholz

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K071456